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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/535,351	04/14/2006	Samuel R. Denmeade	50562-P001US	7060	
61060	7590	01/11/2010	EXAMINER		
WINSTEAD PC		AUDET, MAURY A			
P.O. BOX 50784		ART UNIT		PAPER NUMBER	
DALLAS, TX 75201		1654			
		MAIL DATE		DELIVERY MODE	
		01/11/2010		PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/535,351	DENMEADE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 November 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 21-53 is/are pending in the application.  
 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 21-24 and 27-53 is/are rejected.  
 7) Claim(s) 21-24 and 27-53 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 18 May 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group III, claims 21-53, and the peptide of the invention of SEQ ID NO: 9 (artificial/synthetic peptide sequence of GKAFFR), in the reply filed on 5/7/09 is acknowledged. Claims 25-26 are withdrawn as not being drawn to the elected invention. As noted in the restriction requirement of 12/8/0, the election of the peptide of SEQ ID NO: 9 was an election of invention (not species) as the compound of the elected Group III. As noted SEQ ID NO: 9 is an independent and distinct invention; a distinct search with no overlapping core with any other peptides (art that would be deemed to read on one would not the other, absent evidence to the contrary which was not filed of record).

### ***Claim Objections***

1. Claims 21-24 and 27-53 are objected to because of the following informalities:

The claims have not been amended commensurate in scope with the elected invention of the peptide of SEQ ID NO: 9 (artificial/synthetic peptide sequence of GKAFFR).

Appropriate correction is required.

2. Claims 47 and 49 are objected to because of the following informalities:

It is unclear whether Cisplatinum is to be capitalized or not? (If a Trademark, it must be deleted from the claims and the associated chemical name amended into the claims/specification).

Appropriate correction is required.

***Specification Objection-Sequence Compliance***

The disclosure is objected to because of the following informalities:

In the Notice of Non-Compliant Amendment (9/24/09), Applicant was informed that there was also a lack of sequence compliance in the application (listing, CRF, statement)-

Additionally, Applicant has elected as the compound of the invention the peptide sequence GKAFFR. This is a peptide of 4 or more amino acids and needs a SEQ ID NO:. There is no sequence listing found in the application. Applicant is asked to file a proper sequence listing, claiming the variable genus sequence as SEQ ID NO: 1, the elected peptide of GKAFFR as SEQ ID NO: 2, and any other expressly described/sequenced peptides for which Applicant had described in the specification as having possession of at the time of filing of the invention.

Applicant's filing of the sequence listing and Computer Readable Form (CRF) is acknowledged, however, it has been rejected as flawed. Thus, neither has been entered into the database. A new sequence listing, CRF, and statement is required to be filed before or with response to this Action. Applicant is instructed to call the STIC branch of the UPSTO (Anne Marie Corrigan @ 571-272-2501) to inquire as to how to put the sequence listing/CRF into compliance so they may be entered into the system.

**Applicant is also asked to correct all specification sequence compliance issues, similar to those identified in co-pending SN 11/725,135 (US PUB 20080247950).**

Appropriate correction is required.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-24 and 27-53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 8, and 17-36 of copending Application No. 11/725,135. Although the conflicting claims are not identical, they are not patentably distinct from each other because presently elected peptide of SEQ ID NO: 9 (artificial/synthetic peptide sequence of GKAFFR) is a species of the genus claims of '135 (see. E.g. claims 17, 1-2, 8, copied below). '135, also titled activation of peptide prodrugs by hK2, is drawn to:

17. A composition comprising a prodrug, the prodrug comprising
  - a therapeutically active drug; and
  - a peptide of claim 1,

wherein the peptide is linked to the therapeutically active drug to inhibit the therapeutic activity of the drug, and wherein the therapeutically active drug is cleaved from the peptide upon proteolysis by an enzyme having a proteolytic activity of human kallikrein 2 (hK2).

1. A peptide comprising an amino acid sequence having a cleavage site specific for an enzyme having a proteolytic activity of human kallikrein 2 (hK2), wherein the peptide is 20 or fewer amino acids in length.
2. The peptide of claim 1, wherein the sequence comprises: the amino acids

$X_4X_3X_2X_1$ ,

wherein  $X_4$  is from 0 to 20 amino acids;  $X_3$  is lysine, serine, alanine, histidine or glutamine;  $X_2$  is arginine, phenylalanine, lysine or histidine; and  $X_1$  is arginine, histidine or lysine.

Wherein claim 8 is drawn to a species peptide that may be e.g. GKAFR (5mer core of Applicant's elected 6mer GKAFR (SEQ ID NO: 9)), which based on the genus claim 2 could add another amino acid and constitute the presently elected peptide. The genus of '135 read in light of it's specification, revealing that the presently elected 6mer GKAFR (SEQ ID NO: 9) is contemplated therein (specification/sequence listing), it would've thus been obvious for the genus to read on the present species, in this situation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Allowable Subject Matter***

Notwithstanding the Double Patenting rejection above, claims 21-24 and 27-53, as drawn to the elected invention of the peptide of SEQ ID NO: 9 (artificial/synthetic peptide sequence of GKAFR); was not found to be reasonably taught or suggested by the prior art of record. As noted above, were the claims amended commensurate in scope with the elected invention of the

peptide of SEQ ID NO: 9, the claims would likely receive favorable consideration (pending no new art is found on the updated search of the art, to be conducted after response hereto).

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 1/4/2010

/Maury Audet/  
Primary Examiner, Art Unit 1654